

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

APR 06 2010

To:

DORSEY & WHITNEY LLP
Attn. Mills, Alicia Griffin
50 South Sixth Street Suite 1500
Minneapolis MN 55402-1498
ETATS-UNIS D'AMERIQUE

446368-895
KEL/MDS/JW

INVITATION TO PAY ADDITIONAL FEES
AND, WHERE APPLICABLE, PROTEST FEE
(PCT Article 17(3)(a) and Rule 40.1 and 40.2(e))

Date of mailing
(day/month/year)

19/03/2010 ✓

Applicant's or agent's file reference

188043/PCT

PAYMENT DUE

within **ONE MONTH** from
the above date of mailing ✓

International application No.

PCT/US2008/067123 ✓

International filing date
(day/month/year)

16/06/2008

Applicant

Response to Invitation to Pay Additional Fees: 4.19.2010

OSTEOTECH, INC.

1. This International Searching Authority

- (i) considers that there are 5 (number of) inventions claimed in the international application covered by the claims indicated on an extra sheet:
- (ii) therefore considers that **the international application does not comply with the requirements of unity of invention** (Rules 13.1, 13.2 and 13.3) for the reasons indicated on an extra sheet:
- (iii) ☒ has carried out a partial international search (see Annex) ☐ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:
see extra sheet
- (iv) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid.

2. Consequently, the applicant is hereby **invited to pay**, within the time limit indicated above, the amount indicated below:

EUR 1.700,00 x 4 = EUR 6.800
Fee per additional invention number of additional inventions currency/total amount of additional fees

3. The applicant is informed that, according to Rule 40.2(c), **the payment of any additional fee may be made under protest**, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive, where applicable, subject to the payment of a protest fee.

Where the applicant pays additional fees under protest, the applicant is hereby invited, within the time limit indicated above, to pay a protest fee (Rule 40.2(e)) in the amount of

EUR 750,00 (currency/amount)

Where the applicant has not, within the time limit indicated above, paid the required protest fee, the protest will be considered not to have been made and the International Searching Authority will so declare.

4. ☐ Claim(s) Nos. _____ have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Joëlle Gerber

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-44, 96-112

A method of treating tissue comprising: providing tissue; heating the tissue in the absence of oxygen.

2. claims: 45-65

A method of treating cortical bone comprising: providing cortical bone; treating the cortical bone to disrupt the collagen structure of the bone; wherein the cortical bone retains at least approximately 30% of its original strength after treating the cortical bone.

3. claims: 66-95

A method of treating tissue comprising: providing tissue; treating the tissue in supercritical fluid; and removing the tissue from the supercritical fluid.

4. claims: 113-130

An osteoinductive composition composing-tissue, the tissue having been treated to degrade collagen within the tissue and increase the biologic activity of the tissue, wherein the tissue exhibits increased biologic activity when compared to untreated at tissue.

5. claims: 131-141

A tissue-based material treated to improve its remodeling characteristics.

- The application lacks unity within the meaning of Rule 13.1 and 13.2 PCT, since there are several inventions covered by the claims of the present application, which are not so linked as to form a single general inventive concept.

- In the application as originally filed (claims, description and figures) different problems are identified (e.g. degradation of collagen in tissues, drying tissues, sterilization of tissues, improve resorption/remodeling of tissues, etc..) as well as different solutions (e.g. thermal treatment, critical point drying, treatment with supercritical fluids, etc..). The present application contains 6 independent claims; 4 independent method claims and 2 independent product claims. The only common concept linking together the independent claims is the provision of tissue treatments. This general common concept is known from the prior art and therefore not inventive. Thus, there is a

non-unity of invention "a priori" between the independent claims.
- Independent claims 1, 45, 66, 96, 113 and 131 refer to methods for treating tissue and products which are not linked by a single general inventive concept (combination of problem and solution). The requirements of Rule 13.1 are not met and the application lacks unity of invention.

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:

see 'Invitation to pay additional fees'

2. This communication is not the international search report which will be established according to Article 18 and Rule 43.

3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.

4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/216321 A1 (LYU SUPING [US] ET AL) 28 September 2006 (2006-09-28) paragraphs [0011], [0012], [0015] - [0022], [0025], [0027], [0032], [0033], [0037], [0046], [0049] claims 1,3,4,5,14,15,17,26,29,30,31,40,41	1-3,8-9, 14,22, 26,28, 38, 41-43, 96,102, 110-111
X	US 6 217 614 B1 (FAGES JACQUES [FR] ET AL) 17 April 2001 (2001-04-17) column 3, lines 40-55 column 4, lines 1-12,30-33,40-48 column 5, lines 20-31,42-44 column 6, lines 14-16,27-38 ----- -/--	1-3, 6-31, 33-40, 42,44, 96-110, 112

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

* & * document member of the same patent family

COMMUNICATION RELATING TO THE RESULTS
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No

PCT/US2008/067123

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 2003/072677 A1 (KAFESJIAN RALPH [US] ET AL KAFESJIAN RALPH [US] ET AL) 17 April 2003 (2003-04-17)</p> <p>paragraphs [0011], [0013], [0015], [0021], [0045], [0048], [0052], [0053], [0056], [0057]</p>	<p>1, 4-5, 22, 26, 28, 38, 41-42, 96, 100-102, 110</p>
X	<p>EP 0 781 564 A2 (SHIMIZU YASUHIKO [JP]; AMD LTD [JP]) 2 July 1997 (1997-07-02)</p> <p>page 3, lines 30-42 page 4, lines 5-10, 46-58 example 1</p>	<p>1, 4, 8-10, 12, 32, 38, 40, 42</p>

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2006216321	A1	28-09-2006	NONE
✓ US 6217614	B1	17-04-2001	NONE
US 2003072677	A1	17-04-2003	CA 2462717 A1 24-04-2003 EP 1436016 A1 14-07-2004 JP 2005506173 T 03-03-2005 WO 03033035 A1 24-04-2003
EP 0781564	A2	02-07-1997	JP 3476631 B2 10-12-2003 JP 9225018 A 02-09-1997